

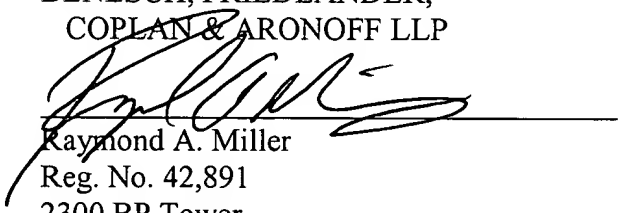
REMARKS

This application was filed on April 10, 2001. It is respectfully requested that this preliminary amendment be entered before examination of this application. These amendments clarify the presently claimed invention and are cosmetic in nature, but they do not add new matter. For Examiner's convenience, Applicant submits herewith a substitute specification pursuant to 37 C.F.R. §1.125.

The Commissioner is authorized to charge all fees due and any additional fees to Deposit Account No. 02-2051.

Respectfully submitted,

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Version with Markings to Show Changes Made

IN THE SPECIFICATION:

Pending paragraph beginning on Page 2, line 2:

The administration of acarbose alone has been shown to be useful in the treatment of diabetes. Although the initial studies conducted herein were conducted with a delayed release formulation [**that allowed partial sustained release administered to stimulate**] to attain sustained release, all indicators from the present invention suggest the formulation of acarbose in a sustained release formulation would have heretofore unexpected benefits. In a sustained release formulation, the ingredient(s) would be a shaped dosage unit having a sustained and regular release of acarbose throughout the small intestine where carbohydrates as a simple sugar are absorbed.

Pending paragraph beginning on Page 9, line 23:

The release pattern of active medicament from the carrier of the present invention can be controlled according to the particular medication and its intended therapeutic effect. [**For a tablet, the release pattern may be varied from about 15 minutes to 4 hours.**] For orally administered tablets, the rate of release may be 4-10 hours, or as desired. Predetermined release patterns of unusually reliable and constant characteristics can be secured. It has been determined that a rate of release of 6-8 hours is particularly suitable for purposes of the present invention.

Pending paragraph beginning on Page 10, line 11

This delivery of sustained-release acarbose to the small intestine will produce maximum inhibition of carbohydrate utilization, resulting in weight control. A study was designed to determine the efficacy and safety of delayed-release acarbose tablets, in conjunction with diet and exercise, as a potential weight-control agent in non-diabetic, healthy, obese patients over a period of 16 weeks. Laboratory data was obtained to monitor systemic side effects, including the changes in levels of serum cholesterol, triglycerides and lipoprotein. Over the 16-week period, patients in Group A received 50 mg. enteric-coated acarbose tablets. All patients received acarbose 25 mg. t.i.d. during a 2-week pretreatment acclimatization phase. All patients underwent a 4-week follow-up phase where they ingested placebo tablets.